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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,486	03/08/2001	Alan H. Shikani	20355-PA	4743

7590 07/28/2003

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EXAMINER
PATEL, MITAL B

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 07/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/801,486	SHIKANI, ALAN H.	
	Examiner	Art Unit	
	Mital B. Patel	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☒ The proposed drawing correction filed on *29 October 2002* is: a)☒ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Amendment/Arguments

1. Applicant's arguments filed 10/29/02 have been fully considered but they are not persuasive.

2. In response to Applicant's arguments that Wapner does not disclose the use of a viscoelastic polymer construction, it should be noted that the Examiner has rejected the claims under 35 U.S.C. 103(a) with Wapner as the base reference and Belfer et al as the teaching reference with respect to the viscoelastic polymer construction. Furthermore, Applicant admits on page 10 of the arguments that the viscoelastic polymer has been used for years in the medical field and as such does not attest to the novelty of the use of the viscoelastic polymer for patient comfort.

3. In response to Applicant's arguments with respect to Wapner does not disclose or suggest a rapid connector means as claimed by the applicant, again please note that the Examiner has rejected the claims under 35 U.S.C. 103(a) with Wapner as the base reference and Tuman as the teaching reference with respect to the rapid connector means. Furthermore, the Velcro as taught by Wapner is also deemed to be a rapid connector means and as such the means as claimed by the Applicant are mechanical expedients of Velcro. Furthermore, Applicant argues that the device of Tuman is not for a tracheostomy tube but rather for an endotracheal use. However, the Examiner used the reference to show a teaching of a rapid connector means not for the intended use of the device.

4. In response to applicant's argument that Belfer et al and Lane are nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the use of the Belfer and Lane references is to address the particular problem the Applicant is concerned with, specifically providing comfort to the patient by the use of a viscoelastic polymer as taught by Belfer and providing a means for adjustment of a strap or band as taught by Lane.

5. In response to Applicant's remarks with respect to the Declaration it should be noted that the declaration is not persuasive with respect to showing evidence of non-obviousness to persons skilled in the art. Applicant would clearly benefit or gain from the patenting of the application and without providing convincing evidence, the Examiner is not apt to give weight to the declaration as would be the case if there was supporting evidence and the declaration was from a disinterested party. Furthermore, the commercialization of the device has no bearing on the obviousness or non-obviousness of an invention.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wapner (US 4331144) in view of Tuman (US 5205832) further in view of Belfer et al (US 5918598).

8. **As to claim 18**, Wapner teaches a tracheostomy tube adapted to be disposed on the neck of a patient comprising a neck plate **18** having a given width and further having a first end, an opposite second end and an opening between the first and second ends, a cannula **14** being received in the opening in the neck plate, the cannula adapted to be inserted into the throat of the patient, a first band **10** formed on the first end of the neck plate; the first band having a given length and further having a free end distally; a second band **12** formed on the second end of the neck plate, the second band having a shorter length than the first band and further having a free end distally of the neck plate; whereby the respective bands may be quickly and conveniently fitted around a patient's neck, and whereby the tracheostomy tube may be adapted to be inserted into the patient's throat and rapidly mounted thereto without discomfort and without irritation to the patient. First, Wapner fails to specifically teach the first and second band being formed integrally. However it would be obvious for one of ordinary skill in the art to make the bands integral with the neck plate for ease of manufacture. Second, Wapner fails to specifically teach each of the first and second bands having a width which is smaller than the width of the neck plate and blending in a curved transitional manner into the neck plate to form a unitary structure. However, Applicant has not set forth how the width of the bands being smaller than the width of the neck plate provide an

advantage over the prior art or solve a stated problem or provide an unexpected result. Therefore, one of ordinary skill in the art would expect the band as taught by Wapner to work/ function equally as well despite the difference in width between the band and the neck plate. Furthermore, it would be obvious to one of ordinary skill in the art to vary the width of the band through observation and experimentation. Third, Wapner fails to specifically teach the means for being rapidly releasably connected as set forth in the specification in view of the means plus function language set forth in the claim, in which case the means is a buckle type quick-release fastener. However, Tuman does teach a buckle type means for being rapidly releasably connected so that the device can be released quickly. Therefore, it would be obvious to one of ordinary skill in the art to replace the Velcro means of Wapner with the quick-release means of Tuman, so that it is easier and quicker to connect and disconnect the bands from each other. Finally, Wapner fails to teach the neck plate and the bands formed from a viscoelastic polymer. However, Belfer does teach the use of a viscoelastic polymer for fitting and sealing to the contours of the individual and being able to maintain the seal on the patient even when the patient is moving or when stretching, pressing, or shearing forces are applied. Therefore, it would be obvious to one of ordinary skill in the art to make the neck plate and bands of the viscoelastic polymer so that the neck plate and bands will not only form a proper seal on the patient but also will move with the patient without providing discomfort to the patient.

9. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wapner in view of Tuman in view of Belfer et al and further in view of Lane (US 5555569).

10. **As to claim 19**, the above combination of Wapner/Tuman/Belfer teaches essentially all of the limitations except for an adjustment means attached to at least one of the bands such that the at least one of the bands may be shortened or lengthened for the comfort of the patient. However, Lane does teach the use of adjustment means to adjust or tighten the device on the wearer. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Wapner/Tuman/Belfer to include adjustment means so that the device can be adjusted or tightened when in use.

Conclusion

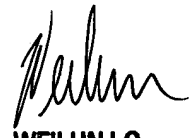
11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 703-306-5444. The examiner can normally be reached on Monday-Friday (8:00 - 4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on 703-308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are 703-306-4520 for regular communications and 703-306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



mbp
January 15, 2003

WEILUN LO
SUPERVISORY PATENT EXAMINER
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